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GENENTECH, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GENENTECH, INC.,

Plaintiff,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania non-profit corporation,

Defendant.

Case No. 5:10-CV-2037-LHK (PVT)

PLAINTIFF'S NOTICE OF MOTION AND MOTION TO FILE FIRST AMENDED COMPLAINT AND FIRST AMENDED ANSWER; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Date: May 12, 2011
Time: 1:30 p.m.
Dept: Courtroom 4, Fifth Floor
Judge: Hon. Lucy H. Koh

Date Comp. Filed: May 11, 2010

Trial Date: None set.

[REDACTED – PUBLIC VERSION]

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NOTICE OF MOTION

PLEASE TAKE NOTICE that on May 12, 2011, at 1:30 p.m. or as soon thereafter as the matter may be heard before The Honorable Lucy H. Koh, 280 South 1st St., San Jose, California, plaintiff and counterclaim defendant, Genentech, Inc. will and hereby does move this Court pursuant to Rule 15(a) of the Federal Rules of Civil Procedure for an order granting leave to file its First Amended Complaint and First Amended Answer. This motion is based on this Notice and the below Memorandum of Points and Authorities, the supporting Declaration of Sarah B. Faulkner in Support of Motion for Leave to Amend ("Faulkner Decl.") filed herewith, the amended pleadings and exhibits, reply memoranda that may be filed, the argument of counsel, the case record, and any documentary evidence that may be presented at the time of the hearing. Plaintiff's proposed First Amended Complaint is attached hereto as Exhibit 1 and proposed First Amended Answer is attached hereto as Exhibit 2.

RELIEF REQUESTED

Genentech seeks an order granting leave to file a First Amended Complaint and First Amended Answer to address new claims and defenses discovered after Genentech filed its initial complaint and answer. Genentech respectfully requests that the Court grant this motion for several reasons: (1) Genentech has not acted in a dilatory manner or in bad faith; (2) defendant The Trustees of the University of Pennsylvania ("University of Pennsylvania") would not be prejudiced by the filings; and (3) the deadline for amending pleadings set by the Court at the initial CMC has yet to pass.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Mindful that flimsy inequitable-conduct allegations commonly infect patent litigation, Genentech intentionally did not plead a cause of action for inequitable conduct when it filed its Complaint. Discovery from University of Pennsylvania has revealed what nobody could have expected: that the named inventors on the patent-in-suit (U.S. Patent No. 6,733,752) and prosecuting counsel perpetrated three distinct frauds on the U.S. Patent and Trademark Office during the ten-year prosecution history that were central to the '752 patent's issuance:

1) Two inventors on the '752 patent, Makoto Katsumata ("Katsumata") and Mark Greene ("Greene") *completely misrepresented* the results of the critical experiments to create support for the effectiveness of the claimed method of treatment;

2) Compounding this deception, Katsumata and Greene further misrepresented to the PTO, during prosecution of the '752 patent, that their experiments allowed them to specify a mechanism of action (called "down regulation") in the '752 patent claims, when Katsumata and Greene knew that their peers in the scientific community had previously criticized those *very same experiments for failing to show down regulation*; and

3) After discovering that University of Pennsylvania's 8 year odyssey to convince the PTO to grant it a patent was going to fail because University of Pennsylvania had made an improper filing in its patent application that caused the application to lapse, University of Pennsylvania's representative, Mitchell Bernstein, made false statements about the events surrounding that improper filing in two different petitions he filed in order to deceive the PTO into reviving and issuing the '752 patent.

These revelations more than justify the proposed amendments to add a cause of action for inequitable conduct, which carefully details "the particularized factual bases" that underpin each of the three frauds such that the Court may understand "'in detail . . . the who, what, when, where, and how' of the alleged fraud[s]." *Exergen Corp. v. Wal-Mart Stores, Inc.,* 575 F.3d 1312, 1327 (Fed Cir. 2009). Consistent with the federal policy favoring liberal amendment of pleadings, Genentech respectfully moves to amend its complaint and answer before the deadline set by the Court has run and submits that leave to amend is proper here because the proposed amendments would not be futile, are made in good faith and without undue delay, and could not result in any prejudice to University of Pennsylvania.

II. BACKGROUND

Genentech filed its complaint in this action on May 11, 2010. That complaint seeks declaratory judgment of noninfringement and invalidity of University of Pennsylvania's '752 patent. The '752 patent names three inventors, Drs. Mark Greene, Makoto Katsumata, and Jeffrey Drebin, all of whom were employees of University of Pennsylvania. Dkt. 7 (Counterclaim, ¶ 3). The '752 patent recites 17 method claims, all directed toward "inhibiting development into breast cancer cells of breast cells overexpressing p185 in an individual in need of such inhibition" by administering to that individual an antibody "in sufficient amount to down regulate the overexpressed p185." Dkt. 1, Ex. A, claim 1. University of Pennsylvania filed its Answer and Counterclaim for infringement on July 12, 2010. Dkt. 7. Genentech answered University of Pennsylvania's counterclaims on August 2, 2010. Dkt. 15. The parties stipulated to a deadline for amending pleadings of February 21, 2011. Dkt. 18.

Since that time, as described more fully below, Genentech has discovered through documentary evidence produced by University of Pennsylvania, deposition testimony from Dr. Katsumata on December 3, 2010, and deposition testimony from Mr. Bernstein, facts showing that inventors Katsumata and Greene, and the representatives of University of Pennsylvania, made numerous false representations to the PTO during prosecution of the '752 patent application with the specific intent to deceive the PTO into granting the '752 patent. University of Pennsylvania's fraud, including Katsumata, Greene, and/or Bernstein, on the PTO renders the '752 patent unenforceable. In addition, Genentech has discovered through deposition testimony and other recently produced information, that University of Pennsylvania's patent agent for the '752 patent, Mitchell Bernstein, made material and false misrepresentations to the PTO to secure the grant of the '752 patent.

Based on these discoveries, Genentech now seeks leave to file its proposed First Amended Complaint and First Amended Answer, which include the newly-discovered cause of action and affirmative defense of unenforceability based on inequitable conduct. *See* Proposed First Amended Complaint, attached hereto as Exhibit 1, at ¶¶ 33-137; Proposed First Amended Answer, attached hereto as Exhibit 2, at ¶¶ 21-124. Prior to filing of this motion, Genentech

conferred with University of Pennsylvania to notify University of Pennsylvania of the amendments and to seek a stipulation to file this motion unopposed. University of Pennsylvania refused. *See* Faulkner Decl., ¶ 22.

III. ARGUMENT

Rule 15(a) of the Federal Rules of Civil Procedure directs that leave to amend "shall be freely given when justice so requires." In deciding whether to grant leave to amend, "a court must be guided by the underlying purpose of Rule 15—to facilitate decision on the merits rather than on the pleadings or technicalities." *United States v. Webb*, 655 F.2d 977, 979 (9th Cir. 1981). This policy of favoring amendments to pleadings "is to be applied with extreme liberality." *Morongo Band of Mission Indians v. Rose*, 893 F.2d 1074, 1079 (9th Cir. 1990). "Four factors are commonly used to determine the propriety of a motion for leave to amend. These are: bad faith, undue delay, prejudice to the opposing party, and futility of amendment." *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 186 (9th Cir. 1987). Genentech's proposed amended pleadings satisfy each of these factors.

A. Genentech's proposed amendments are not futile.

Genentech's proposed amendments are not futile because the elements of inequitable conduct are present here and have been properly plead under Rule 9(b) of the Federal Rules of Civil Procedure. "[F]ailure to disclose material information, or submission of false material information, coupled with an intent to deceive or mislead the PTO, constitutes inequitable conduct." *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1128 (Fed. Cir. 2006). Here, Genentech has alleged specific facts showing that named inventors of the '752 patent, Katsumata and Greene, as well as its counsel Bernstein, committed fraud on the PTO by misrepresenting material facts with the specific intent to deceive the PTO about the patentability of claim 1. Moreover, Genentech has pleaded the circumstances of inequitable conduct with the requisite particularity under Rule 9(b) by identifying the specific who, what, when, where, and how of the material misrepresentations before the PTO, as well as underlying facts from which the Court may reasonably infer that Katsumata and/or Greene (1) knew of the falsity of the material misrepresentations, and (2) misrepresented these facts with a specific intent to deceive

the PTO. *Exergen Corp.*, 575 F.3d at 1328-29.

1. Genentech has properly pleaded inequitable conduct based on Katsumata and Greene's falsification of data in the '752 patent specification.

First, and as described more specifically below and in Genentech's amended pleadings, Genentech has properly alleged specific facts showing that Katsumata and/or Greene falsified and misrepresented to the PTO the only data in the '752 patent specification supporting the patentability of claim 1 in the '752 patent. Claim 1 is the '752 patent's only independent claim. It addresses a "method of inhibiting development into breast cancer cells of breast cells that overexpress p185" by administering an antibody that "specifically binds to p185 in sufficient amount to down regulate the overexpressed p185 and inhibit the development of said breast cells that overexpress p185 into breast cancer cells." 'Ex. A to Declaration of Sarah B. Faulkner ("Faulkner Decl"),'752 patent cl. 1.

To support claim 1, Katsumata and Greene cited data from their experiments in transgenic mice purporting to demonstrate the preventative effect of antibody treatment on the development of breast tumors that overexpress the p185 protein. Katsumata and Greene reported this data in Example 2 of the '752 patent, which describes experiments on a group of mice treated with lower doses of antibody and a group of mice treated with higher doses of antibody. *Id.* at 6:64-67, 7:38-50. As to the high-dose group, Katsumata and Greene represented that "6 of 12 mice in [the high-dose treatment] group (50%) remained free of tumors at more than 90 weeks of age." *Id.* at 7:66-8:1.

Based on the results of their high-dose experiment, Katsumata and Greene represented to the PTO that the antibody treatment method described in claim 1 could effectively suppress tumor development. *Id.* at 8:1-4. They proclaimed that their data, i.e., that "(50%) of mice did not develop tumors even after ninety weeks of age," "*demonstrate[] for the first time* that immunological manipulations of $p185^{neuT}$ can effectively prevent the development of genetically induced breast tumors in a rodent model." *Id.* at 7:3-8 (emphasis added).

Documents produced by University of Pennsylvania and Katsumata's testimony in this case have revealed that Katsumata and Greene misrepresented the results of their high-dose

experiment. Contrary to their report that six of twelve mice from the high-dose experiment remained tumor-free for over 90 weeks, the University of Pennsylvania records show that [redacted] In fact, according to the records produced by University of Pennsylvania, [redacted]

Katsumata and Greene's misrepresentation cannot be dismissed as a typographic error or accident, because [redacted] Genentech has properly alleged, on information and belief based on these facts, that Katsumata and Greene acted with the specific intent to deceive the PTO about claim 1's patentability.

Moreover, Genentech has specifically alleged that the misrepresented data was material to patentability because the experiment offers the *only* data in the patent application to support a claim to a method that "inhibits development into breast cancer cells of breast cells that overexpress p185." Ex. A at cl. 1. Likewise, during prosecution of the '752 patent, and as alleged specifically in the proposed amended pleadings, Katsumata and Greene repeatedly relied on the misrepresented data to support the pending claims.

Thus, Genentech has alleged facts sufficient to infer that Katsumata and Greene's representation to the PTO that "6 of 12 mice in [the high-dose treatment] group (50%) remained free of tumors at more than 90 weeks of age," Ex. A. at 7:66-8:1, was a false and deceptive statement that, upon information and belief, was intended to mislead the PTO Examiner to believe that the '752 patent discloses a method of inhibiting development into breast cancer cells

of breast cells that overexpress p185. Accordingly, the foregoing specifically plead facts support Genentech's newly-added claims and defenses alleging inequitable conduct.

2. Genentech has properly pleaded inequitable conduct based on Katsumata and Greene's deliberate misrepresentation to the PTO that the '752 patent's specification supports claim 1's down-regulation requirement.

The '752 patent claims a "method of inhibiting the development into breast cancer cells of breast cells that overexpress p185" by administering an antibody that "specifically binds to p185 *in sufficient amount to down regulate the overexpressed p185*." Ex. A. at cl. 1 (emphasis added). The patentees added this down-regulation requirement specifically to overcome the PTO's rejection of a former version of claim 1 for lack of enablement under 35 U.S.C. § 112. The examiner rejected the former version of claim 1 because "[t]he specification [did] not disclose how binding of the claimed antibodies to p185 of normal cells in humans could prevent transformation from normal cells to tumor cells, and/or prevent the overexpression of neu oncogene from normal cells." April 24, 2001 Final Rejection by USPTO of U.S. Application No. 08/525,800, Ex. G (emphasis added).

In response, on August 24, 2001, Katsumata and Greene amended claim 1 to cover "an antibody which specifically binds to p185 in sufficient amount to down regulate the oncogenic activity of overexpressed p185." August 24, 2001 Response and Amendment for U.S. Application No. 08/525,800, Ex. H at 2. On July 1, 2003, Katsumata and Greene further amended claim 1 to its current form, which claims "an antibody which specifically binds to p185 in sufficient amount to down regulate the overexpressed p185." July 1, 2003 Amendment for U.S. Application No. 08/525,800, Ex. I at 2.

In persuading the PTO to accept the 2003 amendment, Katsumata and Greene represented that there was support for this down-regulation limitation "throughout the specification, e.g., in Examples 1 and 2 and in the text [of the specification] set forth at page 14, lines 12-23." *Id.* at 5. That text represents, in pertinent part, that "[t]he data indicate[] that continuous down-regulation of the p185neuT molecule leads to tumor growth suppression in a dose-dependent manner. The antibody mediated dose-dependent tumor suppression shown here suggests that the continuous down-regulation of p185neuT diminishes the activity of necessary

oncogenic factors in tumorigenesis." U.S. Application No. 08/525,800, Ex. J at 14.

Genentech has properly alleged that Katsumata and Greene's foregoing statements to the PTO in support of the down-regulation amendment were false and deceptive and constituted inequitable conduct. *See id.*

a. Peer-reviewed journals repeatedly rejected as unsupported Katsumata and Greene's assertion that the data disclosed in the '752 patent demonstrated down-regulation of the receptor.

In 1994, more than 9 years before amending the '752 patent to claim down-regulation of the p185 receptor as the mechanism of tumor suppression, on information and belief, Katsumata and Greene submitted the very same data disclosed in Example 2 of the '752 patent to a leading scientific journal, *Science*, for publication. *Science* rejected the authors' manuscript, in part, because the proffered data did not support the contention that the antibody down-regulated the p185 receptor. For instance, one peer reviewer scolded Katsumata and Greene because "[t]here are no data presented showing that the monoclonal [antibody] used actually down-regulates p185 under the circumstances employed here." *See* February 9, 1994 Letter from Managing Editor of *Science*, Ex. K at UP0066896.

Katsumata and Greene did not protest *Science*'s rejection of the manuscript, but rather implicitly agreed by conducting a new set of experiments, under totally different conditions from the previous experiments, designed to show down-regulation. In November 1994, Katsumata and Greene submitted a revised manuscript including the new down-regulation experiments for publication in the journal *Nature Medicine*.

Notwithstanding the addition of the new experiments, *Nature Medicine* also rejected the paper, in part, because the authors' down-regulation claims were unfounded. One peer reviewer identified as the "major criticism" of the paper the authors' "attempt to analyze the mechanism underlying the inhibition of tumor formation in this experiment." *See* February 23, 1995 letter from *Nature Medicine*, Ex. L at UP0067153. Likewise, another peer reviewer criticized the authors' down-regulation data as "flawed" and "difficult to interpret," and urged the authors to conduct "additional studies" to support their down-regulation claim. *Id.* at UP0067152. Even after yet another round of revisions to the manuscript, another peer reviewer criticized the

authors' evidence of down-regulation as "interesting but not yet convincing." *See* May 5, 1995 Letter from Adrian J. Ivinson, Senior Editor at *Nature Medicine*, Ex. M at UP0067013. Only after a third round of revisions did *Nature Medicine* finally agree to publish the paper with the down-regulation claims. *See* Katsumata M, Okudaira T, Samanta A., Clark D, Drebin JA, Jolicoeur P, Greene MI., Prevention of breast tumour development in vivo by downregulation of the p185neu receptor. *Nature Medicine* 1(7):644-648, July 1995, Ex. N. Katsumata and Greene did not disclose to the PTO any of the additional experiments they conducted to substantiate their down-regulation claims. Nor did they disclose the 1995 *Nature Medicine* publication to the PTO.

In light of the prior rejections and reviewer comments from *Science* and *Nature Medicine* in 1994 and 1995, both Katsumata and Greene knew, on information and belief, that the data in the '752 patent in fact did not "indicate[] that continuous down-regulation of the p185neuT molecule leads to tumor growth suppression." Ex. A at 8:40-43. Indeed, during deposition, Katsumata admitted [redacted] *See* Ex. C at 168:10-169:7.

Thus, Katsumata and Greene knew, on information and belief based on these facts, that the data in the '752 patent specification did not support the July 1, 2003 amendment claiming "an antibody which specifically binds to p185 in sufficient amount to down regulate the overexpressed p185." Ex. I at 2.

b. Katsumata and Greene knew, on information and belief, that the antibody dose disclosed in the patent does not achieve down-regulation.

The '752 patent's high-dose experiment followed a dosing regime of 10 µg *twice* weekly, which the inventors, including Katsumata and Greene, represented in the patent leads to "continuous down-regulation of the $p185^{neuT}$ molecule" and tumor suppression. Ex. A at 8:40-43. The experiments that Katsumata and Greene devised to demonstrate down-regulation of the

p185 receptor and published in the undisclosed 1995 *Nature Medicine* reference used a much higher, *daily* 10 µg antibody dose. *See* Ex. N at 646.

[redacted]

Moreover, *Nature Medicine*'s peer reviewers criticized Katsumata and Greene's 1995 *Nature Medicine* paper for substantially increasing the dosage used to show down-regulation of the p185 receptor over that used in the experiments disclosed in Example 2 of the '752 patent. One peer reviewer, for example, observed that the down-regulation data were "flawed" and "difficult to interpret" because "the antibody schedule was far more aggressive . . . than was the antibody schedule that was used in the actual therapeutic trial . . . ." *See* Ex. L at UP0067152. A later peer reviewer cautioned Katsumata and Greene to clarify "the apparent requirement of a daily treatment schedule to produce [down-regulation]." *See* Ex. M at UP0067013 (emphasis added).

On information and belief based on the foregoing facts, Genentech has properly alleged that [redacted] (3) as

coauthors of the 1995 *Nature Medicine* reference and named inventors of the '752 patent, Katsumata and Greene knew that the antibody dose disclosed in the '752 patent in fact does not "specifically bind[] to p185 in sufficient amount to down regulate the overexpressed p185." Ex. A at 8:54-55.

In light of the facts alleged in Sections 2(a) and 2(b), Genentech has properly alleged that Katsumata and Greene, on information and belief, knew that the data in the '752 patent specification was not sufficient to support the p185 down-regulation amendment to claim 1 and that the antibody dose disclosed in the '752 patent in fact did not achieve p185 down-regulation. Despite this knowledge, Katsumata and Greene represented to the PTO that the examiner could find support for the down-regulation amendment to claim 1 "throughout the specification, e.g., in Examples 1 and 2 and in the text set forth [in the patent]," specifically that "[t]he data indicate[] that continuous down-regulation of the $p185^{neuT}$ molecule leads to tumor growth suppression in a dose-dependent manner." Ex. I at 2. Thus, Genentech has pleaded facts sufficient to infer that Katsumata and Greene made the foregoing material misrepresentations to the PTO in support of the down-regulation amendment with the specific intent to deceive the PTO about claim 1's patentability.

Moreover, Genentech has properly alleged that Katsumata and Greene's false and misleading statements to the PTO in support of the down-regulation amendment would have been material to the PTO examiner in determining whether one of ordinary skill in the art would conclude that there was adequate written description in the specification for the down-regulation amendment to claim 1, whether the specification enabled the down-regulation amendment to claim 1, and/or whether the inventors had reduced the claimed invention to practice when they filed their application. Accordingly, the foregoing specifically pleaded facts support Genentech's newly-added claims and defenses alleging inequitable conduct.

3. University of Pennsylvania's Counsel Made False Statements to Mislead the PTO into Reviving and Granting the '752 Patent

In April of 2001, the PTO issued a final rejection of University of Pennsylvania's patent application that eventually issued as the '752 patent (i.e., U.S. Application No. 08/525,800, or

the '800 application). In that rejection, the PTO examiner concluded that all of University of Pennsylvania's then-pending claims were unpatentable. University of Pennsylvania's then-counsel, Mark DeLuca tried several things to change the Examiner's mind. First, he and Dr. Greene met with the Examiner in June of 2001. Then, on August 24, 2001, he filed an amendment to the claims and additional arguments in support of the amendments. Hearing nothing back from the PTO, on October 23, 2001,, Mr. DeLuca filed a notice of appeal in the '800 application.

In early January of 2002, University of Pennsylvania's counsel Mark DeLuca faced a looming deadline to file an appeal brief in the '800 application. Instead of filing that appeal brief, Mr. DeLuca decided to file a "request for continued examination" (RCE). However, U.S. law prohibited University of Pennsylvania from using this procedure in the '800 application. Mr. DeLuca, thus, improperly requested continued examination in the '800 application on January 8, 2002.

On January 15, 2002, the PTO responded to Mr. DeLuca's August 24, 2001 amendment and arguments, finding them unpersuasive. Then, on January 17, 2002, the PTO received University of Pennsylvania's notice of appeal that had been filed by DeLuca on October 23, 2001. Next, on January 28, 2002, the PTO granted University of Pennsylvania's request for a three-month extension of time that DeLuca filed with his notice of appeal on October 23, 2001. This extension of time was necessary to keep the '800 application pending up to the date Mr. DeLuca filed his notice of appeal (i.e., up to October 24, 2001). And, finally, the PTO began processing the improper RCE on January 28, 2001, forwarding it to the PTO Examiner for review on February 2, 2002.

According to well-established PTO rules and procedures, a patent applicant has two months to file an appeal brief after the date the PTO actually receives the applicant's notice of appeal. As is plainly apparent from the official records of the '752 patent, the PTO received University of Pennsylvania's notice of appeal on January 17, 2002. This set the deadline for University of Pennsylvania to file its appeal brief as March 17, 2002. University of Pennsylvania, however, never filed its appeal brief. As a consequence, under PTO rules and

procedures, University of Pennsylvania's appeal proceeding terminated on March 17, 2002, and the '800 application went abandoned on March 18, 2002.

The PTO, not recognizing that the RCE DeLuca filed was improper, incorrectly resumed examination of the '800 application and issued a new non-final rejection on April 10, 2002. In June of 2002, University of Pennsylvania abruptly replaced Mr. DeLuca – who had been prosecuting the '800 application for nearly 7 years – with Mitchell Bernstein. Mr. Bernstein filed a response and amendment to the April 10, 2002 rejection on October 10, 2002. Mr. Bernstein then conducted at least 8 interviews with the PTO Examiner handling the '800 application between June 3, 2003 and August 14, 2003. The PTO, for unknown and undocumented reasons, withdrew all of its rejections and allowed the '752 patent on December 3, 2003.

Sometime after he began work on the '800 application, Bernstein recognized that DeLuca had improperly filed the RCE. He also recognized that the '800 application had gone abandoned on March 18, 2002, before the PTO resumed examination of it on April 10, 2002. So, Mr. Bernstein contacted the PTO, and was affirmatively told that the '800 application was abandoned. This not only removed any question he had that the '800 application might yet be viable; it also meant he understood that the '800 application would not issue as a patent unless Mr. Bernstein did something to convince the PTO to revive the application, and enter the three amendments he filed between October 10, 2002 and August 16, 2003.

Bernstein, however, faced a significant impediment; the '800 application had gone abandoned *before* the PTO had resumed examination of it. So, Bernstein needed something to bridge the gap. Bernstein reviewed the file wrapper of the '800 application, and found that DeLuca had conditionally requested an extension of time to file his appeal brief – from December 24, 2001 until January 24, 2001 – during the time DeLuca was waiting for the PTO to receive University of Pennsylvania's notice of appeal. But there was no evidence in the official records of the '800 application that the PTO had granted this extension of time. And for good reason – it was entirely unnecessary, because the appeal brief filing deadline for University of Pennsylvania had not even begun to run! There also was no evidence that University of

Pennsylvania had paid the required fee for this extension of time. In short, the evidence before Bernstein vividly established that the PTO had *not* granted University of Pennsylvania a one-month extension of time to file its appeal brief back in January of 2002.

Bernstein, despite this record, prepared and filed two petitions to revive the abandoned '800 application. Bernstein anchored his reasons why the PTO should revive the '800 application on his false statement that the PTO had actually granted the one-month extension of time back in January 2002. In his February 10, 2004 petition, Bernstein stated repeatedly that PTO had *actually granted* the extension, and as a result, the '800 application did not go abandoned until April 18, 2002 – after the PTO had improperly resumed examination of the '800 application. The PTO petitions examiner – a different PTO official than those handling examination of the '800 application – reviewed Bernstein's petition, but did not see that the PTO had granted an extension of time to University of Pennsylvania to file its appeal brief. Accordingly, the PTO petitions examiner stated that University of Pennsylvania's "deadline for filing the appeal brief was March 17, 2002." The PTO nonetheless granted University of Pennsylvania's February 10, 2004 petition. In so doing, the PTO, reflecting its confusion about the actual status of the '800 application, applied the rules reserved for applications that can be subject to the RCE procedure which the '800 application was not eligible to use.

Bernstein, seeing that the PTO petitions examiner had concluded that University of Pennsylvania's deadline for filing its appeal brief was March 17, 2002, filed a second petition on May 10, 2004. Again, Bernstein stated over and over that the PTO had "actually granted" University of Pennsylvania a one-month extension of time to file its appeal brief, and that this had the effect of making the '800 application go abandoned on April 18, 2002, rather than March 17, 2002 – the date it actually went abandoned. The PTO petitions examiner again granted University of Pennsylvania's petition. Again, the petitions examiner found that University of Pennsylvania's deadline for filing its appeal brief was March 17, 2002. But then the PTO stated that "a petition for one month extension of time was filed on January 28, 2002." The only source of this conclusion was Bernstein's false statements in his two petitions. And, as the record plainly shows, the extension of time that the PTO entered on January 28, 2002 was the

three-month extension of time DeLuca filed on October 23, 2001 to keep the '800 application pending until October 24, 2001 (i.e., long enough to allow University of Pennsylvania to file its notice of appeal on October 23, 2001).

Bernstein knew his statements that the PTO had granted a one-month extension of time in January of 2002 were false. He also knew that if he was unable to convince the PTO to revive the '800 application and enter all of his amendments in 2002 and 2003, the '800 application would never issue as a patent. Thus, he knowingly made false statements that were material to the decision of the PTO to revive the '800 application and issue it as the '752 patent.

B. Genentech has acted in good faith and brought a timely motion to amend its complaint.

Genentech has not engaged in undue delay and is acting in good faith. The parties' stipulated deadline for amending the pleadings is February 21, 2011, and Genentech's motion for leave to amend complies with this deadline. Moreover, Genentech only recently discovered the facts underlying its cause of action for inequitable conduct and promptly brought the appropriate motion for leave to file their proposed amended answer. Genentech has also acted with good faith and proper motive. Indeed, "[t]o oppose a motion for leave to amend on grounds of bad faith, a party must show 'sharp practice' tactics such as, for example, seeking to add a defendant merely to destroy diversity jurisdiction." *SAES Getters S.p.A. v. Aeronex, Inc.*, 219 F. Supp. 2d 1081, 1085 (S.D. Cal. 2002). Here, there is no such tactic being employed—Genentech timely raised this inequitable conduct cause of action shortly after discovering its underlying facts and moved to amend by the stipulated deadline.

C. University of Pennsylvania will not suffer prejudice from allowing Genentech to amend its complaint.

University of Pennsylvania will suffer no prejudice if the Court permits Genentech to add an additional cause of action. Genentech's First Amended Complaint and Answer do not change the nature of the lawsuit, and University of Pennsylvania can discovery in relation to the amended pleadings. Indeed, University of Pennsylvania necessarily has been aware of the relevant facts upon which Genentech's inequitable conduct allegations are based before these issues were discovered by Genentech. Nonetheless, because the lawsuit is still in its initial

stages, the parties will have sufficient opportunity to discover all facts relevant to Genentech's inequitable conduct cause of action.

IV. CONCLUSION

There are cases in which inequitable conduct is not appropriately put at issue. This is not such a case. The inventors and prosecuting counsel repeatedly deceived the PTO to secure the '752 patent. Genentech respectfully requests that the Court grant Genentech leave to file the proposed First Amended Complaint and Answer attached as Exhibits 1 and 2 to the Faulkner Declaration.

Dated: March 25, 2011

Respectfully submitted,

By: */s/ Ashok Ramani*

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